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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,391	11/12/2003	Randal Eckert	59157.8007.US02	5819

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,391	ECKERT ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13-17,19,20,24-27,48,50-52 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-17,19,20,48,50-52 and 54* is/are rejected.

7)☒ Claim(s) *24-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-22-2008 has been entered.

The amendment filed on 2-22-2008 is acknowledged. Claims 1, 13-17, 24, 26, 48, 50-52 and 54 have been amended. Claims 4, 6-12, 18, 21-23, 28-47, 49 and 53 have been canceled.

Election/Restrictions

Applicant's traversal regarding the withdrawal of claim 54 from consideration is acknowledged. As outlined in the previous Office action, claim 54 is directed to an invention that is independent or distinct from the invention originally claimed. The elected invention was limited to compositions comprising a targeting moiety comprising SEQ ID NO:61. Claim 54 is drawn to a fusion peptide comprising SEQ ID NO:70. Consequently, the withdrawal for said claim from consideration is deemed proper. However, given that the specification only discloses two fusion proteins (exemplified by SEQ ID NO:70 and SEQ ID NO:71) and in an effort to expedite prosecution is hereby rejoined. Consequently, claims 1, 13-17, 19-20, 24-27, 48, 50-52 and 54 are pending and currently under examination.

Claim Objections

The objection to claims 1-2, 24 and 47-53 as being drawn, in part, to non-elected inventions is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The provisional rejection of claim 2 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 13 of copending Application No. 10/077,624 is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claims 1-2, 10-11, 13-20, 24-25 and 47-53 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in lieu of the rejection set forth below.

The new matter rejection of claims 1, 24-27 and 49-53 under 35 U.S.C. 112, first paragraph, based on the claim 1 limitation "wherein the targeting moiety is fused in-frame with the anti-microbial peptide..." is withdrawn in light of the amendment thereto.

The new matter rejection of claims 1-2, 10-11, 13-20, 24-27 and 47-53 under 35 U.S.C. 112, first paragraph, based on the claim 1 limitation "specifically killing microbial organisms ..." is withdrawn in light of the amendment thereto.

The rejection of claims 1-2, 24 and 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because said claims recite language drawn to non-elected inventions is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "specifically killing microbial organisms" is withdrawn in light of the amendment thereto.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "wherein the target microbial organism is *Pseudomonas*" is withdrawn in light of the amendment thereto.

The rejection of claims 1-2, 10-11, 13-20, 24-27 and 47-53 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goldenberg (U.S. Patent 5,332,627) is withdrawn in light of the amendment thereto.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13-17, 19-20, 48, 50-52 and 54 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of killing *Pseudomonas* species and *E. coli* utilizing compositions comprising a targeting moiety with the amino acid sequence of SEQ ID NO:61 attached to a antimicrobial peptide moiety, does not reasonably provide enablement for methods of killing any other microbial species utilizing said compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the invention commensurate in scope with these claims.

The aforementioned claims are drawn to compositions useful for the killing of microbial organisms wherein the targeting moieties of said compositions comprise SEQ ID NO:61. The specification however, is silent on which microbial species other than *Pseudomonas* species and *E. coli* said composition would be effective against or how such a composition would be used. In fact, the specification discloses on the page 7-8 bridge that the peptide with the sequence of SEQ ID NO:61 "specifically binds to *Pseudomonas* species, or *E. coli*". Given this disclosure, the skilled artisan has no guidance in using the claimed compositions to kill any microbial species other than *Pseudomonas* species and *E. coli.* People of skill in the art require evidence that a benefit can be derived by the application of a given substance. While the skill in the art of immunology is high, to date, prediction of a therapeutic benefit (effect) for any given composition is quite unpredictable. Moreover, while one may know how to make the composition, no evidence has been provided that illustrates or even suggest that the claimed compositions are capable of providing the claimed effect against a given microbial species, one of skill in the art has not been taught to use the claimed composition to the full breadth of the claims.

Claims 1, 13-17, 19-20, 48, 50-52 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The aforementioned claims are drawn to compositions

useful for the killing of microbial organisms wherein the targeting moieties of said compositions comprise SEQ ID NO:61.The specification however, is silent on which microbial species other than *Pseudomonas* species and *E. coli* said composition would be effective against (i.e. which microbial species present epitopes which would bind SEQ ID NO:61). In fact, the specification discloses on the page 7-8 bridge that the peptide with the sequence of SEQ ID NO:61 "specifically binds to *Pseudomonas* species, or *E. coli*". Given this disclosure, the skilled artisan has no guidance in using the claimed compositions to kill any microbial species other than *Pseudomonas* species and *E. coli.*

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of *Pseudomonas* species and *E. coli* , the skilled artisan cannot envision the microbial species encompassed by the claims

> Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli ,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2datl966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula,

> chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only methods of killing *Pseudomonas* species and *E. coli*, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Conclusion

Claims 1, 13-17, 19-20, 48, 50-52 and 54 are rejected.

Claims 24-27 are objected to as being dependent on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
May 6, 2008